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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,225	09/13/2006	Eric Brown	P07921US01/BAS	8963

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,225	BROWN ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6-8,10-13,16-19 and 21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,14,15 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/14/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *091306 & 062308*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1) Acknowledgment is made of Applicants' preliminary amendment filed 09/13/06.

Election

2) Acknowledgment is made of Applicants' election filed 11/06/08 in response to the lack of unity mailed 10/08/08. Applicants have elected invention I, claims 1-5, 9, 14, 15 and 20. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

3) Claims 1-27 are pending.

Claims 6-8, 10-13, 16-19 and 21-27 are withdrawn have been withdrawn from consideration as not being directed to the elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-5, 9, 14, 15 and 20 are under examination.

Information Disclosure Statements

4) Acknowledgment is made of Applicants' information disclosure statements filed 09/13/06 and 06/23/08. Except for duplicate citation(s), the information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of submission of Applicants' sequence listing, which has been entered on 11/14/06.

Priority

6) The instant application is a national stage 371 application of PCT/US04/11949, filed 04/16/2004, which claims priority to the provisional application 60/463,028, filed on 04/16/2003.

Objection(s) to Specification

7) The instant specification is objected to for the following reason(s):

The use of trademarks in the instant specification has been noted in this application. For example, see page 24 for 'Tween 20'. All trademark recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix l. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to the trademarks, wherever such recitations appear.

Claimed Invention

8) The first full paragraph of page 11; the second full paragraph of page 3; and the first full paragraph of page 9 of the instant specification acknowledge that the 'SAC3' protein is the 19 kDa Efb protein of *S. aureus* that was previously known in the art. Page 9 of the specification further acknowledges that this protein was taught in the art by Boden *et al.* (*Mol. Microbiol.* 12: 599-606, 1994 – Applicants' IDS) and that it has already been sequenced. It is noted that the 'C3 binding region' of the Efb protein of *S. aureus* is defined at lines 27-30 of page 12 of the instant specification as the region 'which includes' the minimum binding region necessary to bind the C3 protein. Active fragments 'containing' this minimum binding region are indicated herein to be included within the scope of the claimed product.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 1-5, 9, 14 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1-3 are vague and indefinite in the use of the abbreviated recitation 'Efb' in the claim language. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained in parentheses.

(b) Claim 9 is indefinite because it has improper antecedent basis in the limitation: 'said protein fragment'. Claim 9 depends from claim 1, which does not include the recitation of 'a protein fragment'.

(c) Claims 2-5, 14 and 15, which depend directly or indirectly from claim 1, are also rejected under 35 U.S.C. § 112, second paragraph, because of the vagueness in the base claim(s) identified above.

Rejection(s) under 35 U.S.C § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> **(e)** the invention was described in-
> **(1)** an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

12) Claims 1-5, 14, 15 and 20 are rejected under 35 U.S.C § 102(e)(1) as being anticipated by Boden *et al.* (US 2002/0173462 A1 - Applicants' IDS) ('462) as evidenced by Lee *et al.* (*J. Biol. Chem.* 279: 50710-50716, 2004 - Applicants' IDS).

Boden *et al.* ('462) taught a fibrinogen-binding Efb protein, including a 19 kDa protein, purified from *S. aureus*, shorter peptides thereof, and the isolated protein fragment, AKTDATIKKEQKLIQAQNLVREFEKTHTVSAHRKAQKAVNLVSFEYKVKKMVLQERID NVLKQGLVR. See sections [0010], [0021], [0026] and [0055]; and line 5 of Figure 11. The isolated Efb protein comprises within it the C-terminal end comprising the above-cited amino acid sequence. See section [0047]. The protein comprising the SEQ ID NO: 12 has an amino acid sequence comprising amino acids 97 to 165 of the *S. aureus* Efb protein. See the amino acid sequence bridging pages 13 and 14. An immunizing composition comprising the Efb protein in 0.5 to 5 micrograms dose (i.e., an amount effective to elicit an immune response or inhibit complement activation) in isotonic saline solution or an adjuvant (i.e., pharmaceutically acceptable vehicle) was used in vaccination of mammals to protect against infections caused by

staphylococcal infections and for diagnostic purposes. See sections [0025], [0032], [0033], [0054] and [0062]; and abstract. That the above-identified protein fragment of the prior art necessarily comprises the C3 binding region from the *S. aureus* Efb protein and has the intrinsic ability to inhibit complement activation is inherent from the teachings of Boden *et al.* ('879) in light of what is known in the art. For example, Lee *et al.* teach that the C3 binding and the complement activity-inhibiting region of the *S. aureus* Efb protein is located at the C-terminal end of the protein that comprises amino acids 97 to 165 amino acids of the *S. aureus* Efb protein. See abstract; the paragraph bridging the two columns on page 50711; first full paragraph under 'Results'; the paragraph bridging pages 50712 and 50713; Table 1; Figure 3; first full paragraph on page 50713; and Figure 6 of Lee *et al.*

Claims 1-5, 14, 15 and 20 are anticipated by Boden *et al.* ('462). The reference of Lee *et al.* is **not** used as a secondary reference in combination with Boden *et al.* ('462), but rather is used to show that every element of the claimed subject matter is disclosed by Boden *et al.* ('462) with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

13) Claims 1-5, 14, 15 and 20 are rejected under 35 U.S.C § 102(b) as being anticipated by Boden *et al.* (US 6,299,879 – Applicants' IDS) ('879) as evidenced by Lee *et al.* (*J. Biol. Chem.* 279: 50710-50716, 2004 - Applicants' IDS).

Boden *et al.* ('879) disclosed a fibrinogen-binding Efb protein, including a 19 kDa protein, purified from *S. aureus*, shorter peptides thereof; the isolated protein fragment, AKTDATIKKEQKLIQAQNLVREFEKTHTVSAHRKAQKAVNLVSFEYKVKKMVLQERID NVLKQGLVR; and the isolated 19 kDa protein expressed recombinantly via *E. coli*. See abstract; lines 27-36 in column 4; column 2; paragraph bridging columns 2 and 3; lines 28-34 in column 6; lines 18 and 19 in column 8; lines 33-37 in column 10; lines 3-7 in column 18; and line 5 of Figure 6. The isolated Efb protein comprises within it the C-terminal end comprising the above-cited amino acid sequence. See the first two full paragraphs in column 9 and line 5 in Figure 6. The protein comprising the SEQ ID NO: 12 has an amino acid sequence comprising amino acids 97 to 165 of the *S. aureus* Efb protein. See the amino acid sequence of SEQID NO: 12 in the middle of columns 27 and 28. An immunizing composition comprising the Efb protein

in 0.5 to 5 micrograms dose (i.e., an amount effective to elicit an immune response or inhibit complement activation) in isotonic saline solution or an adjuvant (i.e., pharmaceutically acceptable vehicle) is used in vaccination of mammals to protect against infections caused by staphylococcal infections and for diagnostic purposes. See lines 56-60 in column 10; lines 48-51 in column 11; last two full paragraphs in column 12; paragraph bridging columns 12 and 13; lines 19-45 in column 13; and abstract. The prior art protein is used for diagnosing bacterial infections caused by *Staphylococcus aureus* strains via ELISA using enzyme-labeled reagent means to detect binding of antibodies to the protein. See the paragraph bridging columns 13 and 14; and lines 10 and 11 in column 14. That the above-identified protein fragment of the prior art necessarily comprises the C3 binding region from the *S. aureus* Efb protein and has the intrinsic ability to inhibit complement activation is inherent from the teachings of Boden *et al.* ('879) in light of what is known in the art. For example, Lee *et al.* teach that the C3 binding and the complement activity-inhibiting region of the *S. aureus* Efb protein is located at the C-terminal end of the protein that comprises amino acids 97 to 165 amino acids of the *S. aureus* Efb protein. See abstract; the paragraph bridging the two columns on page 50711; first full paragraph under 'Results'; the paragraph bridging pages 50712 and 50713; Table 1; Figure 3; first full paragraph on page 50713; and Figure 6 of Lee *et al.*

Claims 1-5, 14, 15 and 20 are anticipated by Boden *et al.* ('879). The reference of Lee *et al.* is **not** used as a secondary reference in combination with Boden *et al.* ('879), but rather is used to show that every element of the claimed subject matter is disclosed by Boden *et al.* ('879) with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Rejection(s) under 35 U.S.C. § 103

14) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

15) Claim 9 is rejected under 35 U.S.C § 103(a) as being unpatentable over Boden *et al.* (US 6,299,879 – Applicants' IDS) ('879) as applied to claim 1 above.

The teachings of Boden *et al.* ('879) are explained above, which do not expressly disclose a diagnostic kit comprising their C3 binding Efb region and means for detecting binding to the same.

However, methods of assembling a diagnostic kit using an art-disclosed protein or peptide product and a detection means was well known and routinely practiced in the art. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a diagnostic kit for the diagnosis of infections caused by *Staphylococcus aureus* strains as taught by Boden *et al.* ('879) using the C3-binding C-terminal peptide or protein fragment and enzyme-labeled reagents of Boden *et al.* ('879). One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of making readily available Boden's ('879) peptide or protein fragment, or for commercializing Boden's ('879) C3-binding C-terminal peptide or protein fragment for diagnostic use, since Boden *et al.* ('879) explicitly taught the use of their product in the diagnosis of bacterial infections and infections caused by *Staphylococcus aureus* strains.
Claim 9 is *prima facie* obvious over the prior art of record.

Remarks

16) Claims 1-5, 9, 14, 15 and 20 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

January, 2009